selection and channeling biases. Because "roll-in" cases were not excluded, the outcomes reflect the effect of a learning curve. During the enrollment phase of the study, considerable emphasis was placed on procedural training and the sharing of best practices. Nonetheless, the possibility of performance bias could not be excluded. The clinical endpoints were objectively defined a priori, and the outcomes were independently determined by a clinical events committee and an echocardiographic core laboratory. Hence, the detection and measurement biases were mitigated but not eliminated. However compelling the data appear to be at this interim analysis, the number of patients followed up out to 3 years was small; hence, our findings should be considered preliminary.

CONCLUSIONS

The results of the TRITON trial have confirmed the safety and efficacy of RDAVR using the Edwards Intuity Valve System. At 3 years, the Intuity valve was associated with a low mean transvalvular gradient and significant LV mass regression. Moreover, compared with standard surgical bioprostheses, the Edwards Intuity might be associated with larger EOAs in smaller valve sizes, a lower risk of PPM owing to the structural valve design, and a low rate of significant postoperative PVL. These hemodynamic benefits were accompanied by significant improvements in patient functional status.

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References

1. Head SJ, Mokhles MM, Osnabrugge RL, Pibarot P, Mack MJ, Takkenberg JJ, et al. The impact of prosthesis-patient mismatch on long-term survival after aortic valve replacement: a systematic review and meta-analysis of 34 observational studies comprising 27 186 patients with 133 141 patient-years. *Eur Heart J*. 2012;33:1518-29.
2. Bleiziffer S, Eichinger WB, Hettich I, Ruzicka D, Wottke M, Bauernschmitt R, et al. Impact of patient-prosthesis mismatch on exercise capacity in patients after bioprosthetic aortic valve replacement. *Heart*. 2008;94:637-41.
3. Mohty D, Dumesnil JG, Echahidi N, Mathieu P, Dagenais F, Voisine P, et al. Impact of prosthesis-patient mismatch on long-term survival after aortic valve replacement: influence of age, obesity, and left ventricular dysfunction. *J Am Coll Cardiol*. 2009;53:39-47.
4. Rahimtoola SH. The problem of valve prosthesis-patient mismatch. *Circulation*. 1978;58:20-4.
5. Ruel M, Al-Faleh H, Kulik A, Chan KL, Mesana TG, Burwash IG. Prosthesis-patient mismatch after aortic valve replacement predominantly affects patients with preexisting left ventricular dysfunction: effect on survival, freedom from heart failure, and left ventricular mass regression. *J Thorac Cardiovasc Surg*. 2006; 131:1036-44.
6. Tasca G, Brunelli F, Cirillo M, DallaTomba M, Mhagna Z, Troise G, et al. Impact of valve prosthesis-patient mismatch on left ventricular mass regression following aortic valve replacement. *Ann Thorac Surg*. 2005;79:505-10.
7. Borger MA, Dohmen P, Misfeld M, Mohr FW. Current trends in aortic valve replacement: development of the rapid deployment Edwards Intuity valve system. *Exp Rev Med Devices*. 2013;10:461-70.
8. Folliguet TA, Laborde F, Zannis K, Ghorayeb G, Haverich A, Shrestha M. Sutureless Perceval aortic valve replacement: results of two European centers. *Ann Thorac Surg*. 2012;93:1483-8.
9. Martens S, Sadowski J, Eckstein FS, Bartus K, Kapelak B, Sievers HH, et al. Clinical experience with the ATS 3f Enable(R) sutureless bioprosthesis. *Eur J Cardiothorac Surg*. 2011;40:749-55.
10. Kocher AA, Laufer G, Haverich A, Shrestha M, Walther T, Misfeld M, et al. One-year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial: a prospective multicenter study of rapid-deployment aortic valve replacement with the Edwards Intuity Valve System. *J Thorac Cardiovasc Surg*. 2013;145:110-5; discussion 115-6.
11. Clavel MA, Webb JG, Pibarot P, Altwegg L, Dumont E, Thompson C, et al. Comparison of the hemodynamic performance of percutaneous and surgical bioprostheses for the treatment of severe aortic stenosis. *J Am Coll Cardiol*. 2009; 53:1883-91.
12. Pibarot P, Dumesnil JG. Prosthetic heart valves: selection of the optimal prosthesis and long-term management. *Circulation*. 2009;119:1034-48.
13. Beckmann A, Funkat AK, Lewandowski J, Frie M, Schiller W, Hekmat K, et al. Cardiac surgery in Germany during 2012: a report on behalf of the German Society for Thoracic and Cardiovascular Surgery. *Thorac Cardiovasc Surg*. 2014;62:5-17.
14. McClure RS, Narayanasamy N, Wiegerinck E, Lipsitz S, Maloney A, Byrne JG, et al. Late outcomes for aortic valve replacement with the Carpentier-Edwards pericardial bioprosthesis: up to 17-year follow-up in 1,000 patients. *Ann Thorac Surg*. 2010;89:1410-6.
15. Forcillo J, Pellerin M, Perrault LP, Cartier R, Bouchard D, Demers P, et al. Carpentier-Edwards pericardial valve in the aortic position: 25-years experience. *Ann Thorac Surg*. 2013;96:486-93.
16. Baumgartner H, Hung J, Bermejo J, Chambers JB, Evangelista A, Griffin BP, et al. Echocardiographic assessment of valve stenosis: EAE/ASE recommendations for clinical practice. *J Am Soc Echocardiogr*. 2009;22:1-23; quiz 101-2.
17. Hahn RT, Pibarot P, Stewart WJ, Weissman NJ, Gopalakrishnan D, Keane MG, et al. Comparison of transcatheter and surgical aortic valve replacement in severe aortic stenosis: a longitudinal study of echocardiography parameters in cohort A of the PARTNER trial (placement of aortic transcatheter valves). *J Am Coll Cardiol*. 2013;61:2514-21.
18. Pibarot P, Dumesnil JG. Hemodynamic and clinical impact of prosthesis-patient mismatch in the aortic valve position and its prevention. *J Am Coll Cardiol*. 2000; 36:1131-41.
19. Kodali SK, Williams MR, Smith CR, Svensson LG, Webb JG, Makkar RR, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med*. 2012;366:1686-95.

Discussion

Dr Y. Joseph Woo *(Stanford, Calif).* My disclosure is that last year at Penn, I was the principal investigator for the Intuity valve trial and had the opportunity to implant both first- and second-generation devices.

Dr Wahlers, I congratulate you and your co-investigators on your excellent presentation, outstanding results, and pioneering leadership in conveying innovative technologies into clinical practice.

With this presentation and the report by Kocher and Borger,[10] the TRITON team has demonstrated high procedural success, shortened crossclamp and bypass times, enhanced minimally invasive approaches, low paravalvular regurgitation rates, excellent midterm clinical outcomes, LV mass regression, and persistent single-digit mean gradients, with particular benefit in the smaller annulus. I have 4 questions.

First, your hypothesis for the mechanism of generating a larger EOA in the smaller annulus is that the balloon expandable stent mechanically widens the LV outflow tract. Did you observe an elevated incidence of transient conduction abnormalities or mechanical interference with mitral valve anterior leaflet mobility or function?

Dr Wahlers. Dr Woo, thank you very much for the question.

I think the balloon expansion widens the outflow tract a little bit but not permanently. We have not seen any dysfunctions leading to pacemaker implantation, reflected by the pacemaker implant rate, which was low or comparable to that with other prostheses.

Also, no interference with the mitral valve anterior leaflet has been reported to date. That might be also related to the, let us say, acceptable height of the prosthesis. The valve is not so deep sitting in the LV outflow tract; thus, we have concluded that it does not interfere.

Dr Woo. Thank you. Second, the size 19 Intuity valve compared well with the reference echocardiographic data of the EOAs of various other bioprostheses. However, when you study the rest of the tabular data and you compare the Intuity valve against the Magna, on which the Intuity was based, the data you presented revealed that the size 23 and 25 Intuity EOAs, even with the expanded LV outflow tract, were actually smaller than the corresponding Magna EOAs. How would you reconcile this?

Dr Wahlers. Well, this is difficult to explain. What I can tell you from the raw data is that we did not have all the values assessed in every individual patient at all follow-up points. That might have influenced the small sizes of the numbers, and we will have to wait for larger patient numbers to correct for that.

Dr Woo. Thank you. Third, based on either perception or direct experience, would you be kind enough to offer any comparisons between this device and another sutureless aortic bioprosthesis widely available in Europe?

Dr Wahlers. That is a good point. I think the advantage of this valve is that one has a conventional valve mounted on a stent, and all other valves have new designs. That is the first point.

So, the new designs have to prove they will have the same durability as that of the Magna design, which has already been proved. That addresses the first point.

The second point is that with the balloon dilatation of the LV outflow tract, I think the fitting will be better in general compared with that of the other valves available and, therefore, more reproducible.

Dr Woo. Thank you. Finally, given relative differences in the magnitude of the procedure and device costs among transcatheter aortic valve replacement, RDAVR, and standard bioprostheses, where do you envision the ultimate niche for rapid deployment or sutureless AVR?

Dr Wahlers. Well, this is a difficult question to answer. If one can purchase this type of prosthesis for the same price as that of a stented prosthesis, I would totally switch in the small sizes. So, it is a question of the policy of the company regarding where to place the costs.

It is really an advantage to use this valve in patients in whom one wants to have a short clamp time. So, for redo procedures, combined procedures in which one has impaired LV function, and, perhaps, also in the small sizes, such as I mentioned, 19 or 21 mm, the valve might provide advantages with regard to the parameters I showed.

Dr Woo. Thank you again for your leadership in advancing the field.

Dr Wahlers. Thank you very much for your kindness.

Dr Hans-Joachim Schäfers *(Homburg/Saar, Germany).* One quick question—you said in your presentation that the pacemaker rate was 6%, which is somewhat greater than that after conventional AVR, and valve related was 3%. How did you differentiate between the 2?

Dr Wahlers. Let me explain the data. If the patient had preexistent disturbances, such bundle branch block, this led more easily to a pacemaker being needed postoperatively. All other pacemaker implantations were counted as directly related to the valve implantation in patients who had not had these problems preoperatively.

We wanted to be very exact in our analysis, and if you compare the percentage 6.9% for early pacemaker implantation, this compares fairly well with the published data for pacemaker rates in patients with a stented bioprosthesis. So, it is not higher, which perhaps was suspected due to the stent design before.